UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

AMERICAN CLINICAL LABORATORY ASSOCIATION, ET AL.,	)	CIVIL NO. 4:24-CV-479-SDJ
Plaintiffs	)	
v.	)	
U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,	)	
Defendants	)	

ASSOCIATION FOR MOLECULAR PATHOLOGY, ET AL.,	)	CIVIL NO. 4:24-CV-824-SDJ
Plaintiffs	)	
v.	)	
U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,	)	
Defendants	)	

BRIEF OF COMPETITIVE ENTERPRISE INSTITUTE AS AMICUS CURIAE IN SUPPORT OF PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

INTEREST OF *AMICUS CURIAE*[1]

Competitive Enterprise Institute ("Amicus") is a nonprofit organization headquartered in Washington, D.C., dedicated to promoting the principles of free markets and limited government. Since its founding in 1984, the institute has focused on raising public understanding of the problems of overregulation. It has done so through policy analysis, commentary, and litigation.

INTRODUCTION

Plaintiffs in these consolidated cases have petitioned this Court to vacate a rule ("the Final Rule") that the U.S. Food and Drug Administration ("FDA") adopted with regard to medical devices and laboratory developed tests. Medical Devices; Laboratory Developed Tests, 89 Fed. Reg. 37,286 (May 6, 2024) (to be codified at 21 C.F.R. § 809.3(a)). Plaintiffs moved for summary judgment in their favor. *See* Dkt. #20, 27. Amicus respectfully submits this brief in support of the motions for summary judgment to suggest to the Court that the Final Rule is incompatible with the statutory text and its context, both in what it retains and in what it adds, and that particularly with regard to the announced phaseout policy, FDA has not exercised its authority consistently with the requirements of the Administrative Procedure Act.

ARGUMENT

I. The Final Rule Conflicts with the Food, Drug, and Cosmetic Act.

A. The Levels of Conflict

In the Final Rule, FDA retained existing language in 21 C.F.R. § 809.3(a) and added the phrase "including when the manufacturer of these products is a laboratory" to its last sentence so that the section reads as follows:

[1] Amicus affirms that no counsel for a party authorized this brief in whole or in part, that no person other than Amicus and its counsel made a monetary contribution to the preparation or submission of this brief, and that all parties consent to the submission of this brief.

> *In vitro diagnostic products* are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h)(1)[2] of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, *including when the manufacturer of these products is a laboratory*.

21 C.F.R. § 809.3(a) (emphasis added).

There are two parts to section 809.3(a), a definition and a declaration. FDA amended the second part, the declaration. The first part defines *in vitro diagnostic products*. The second part of section 809.3(a) declares that what it has defined as in vitro diagnostic products are *devices* as defined in section 201(h)(1) of the Food, Drug, and Cosmetic Act ("the Act"). The amendment to section 809.3(a) adds in vitro diagnostic products manufactured in a laboratory to the in vitro diagnostic products that the rule declares to be devices. FDA refers to in vitro diagnostic products manufactured in a laboratory as laboratory developed tests, LDTs, or IVDs offered as LDTs.

The addition of LDTs is contrary to law because it relies upon an inconsistency between the pre-existing regulatory definition and the statutory definition. Section 809.3(a) defines in vitro diagnostic products, a term not found in section 201(h)(1) of the Act, to include *systems*, a term also not found in section 201(h)(1) of the Act. As will be discussed below, smuggling the extraneous word *systems* into the regulation is essential to bringing LDTs within FDA's definition of in vitro diagnostic products, but it cannot legitimately bring LDTs within the Act's definition of device.

The definition of *device* in the Act, as amended by the Medical Device Amendments of 1976 (MDA),[3] provides:

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[2] The Final Rule unobjectionably changes the citation from section 201(h) to section 201(h)(1).
[3] Pub. L. 94-295, § 3(a)(1)(A), 90 Stat. 539, 575 (1976).

> The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
>
> > (A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> >
> > (B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> >
> > (C) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 360j(o) of this title.

21 U.S.C. § 321(h)(1) (section 201(h)(1) of the Act)).

Section 809.3(a) is not a definition of in vitro reagent, instrument, or any other term in the statutory definition of device. In fact, the term *in vitro reagent* does not appear anywhere in part 809 ("in Vitro Diagnostic Products for Human Use"). Section 809.3(a) is a definition of a different term—*in vitro diagnostic products*. Nonetheless, section 809.3(a) declares that what it defines as in vitro diagnostic products "are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act" even though that section of the Act does not say that in vitro diagnostic products are devices.

The problem with declaring in vitro diagnostic products as defined in section 809.3(a) to be devices is that section 809.3(a) defines in vitro diagnostic products to include not just *reagents* and *instrument*s, words found in the statutory definition of device, but also *systems*, a word not found in the statutory definition of *device*. Section 809.3(a) states, "*In vitro diagnostic products* are those reagents, instruments, and systems intended for use in the diagnosis of disease or other

conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae."

FDA seeks to use the word *systems* to bring LDTs under the rubric of in vitro diagnostic products and from there bring them under the rubric of devices. The second step does not follow from the first. Systems could perhaps be deemed to be in vitro diagnostic products, but it does not follow from this that systems are in vitro reagents or instruments and thus devices. This sleight of hand is like expanding the meaning of *automobile* by defining *vehicular products* to include transportation and then declaring that everything within the definition of vehicular products (such as networks of highways and railroads) is an automobile. *In vitro* is Latin for "in glass." In a medical context it means "observable in a test tube; in an artificial environment."[4] A reagent is "a substance used to produce a chemical reaction so as to detect, measure, or produce other substances."[5] An LDT, as described by FDA, is more than a reagent or an instrument. For that reason, the word in section 809.3(a) that FDA relies upon is *systems*. A system, as FDA envisages it with regard to LDTs, is a much broader concept. The preamble to the Final Rule says that "IVDs include test systems," 89 Fed. Reg. at 37,288, but avoids saying what test systems are. The preamble of the notice of proposed rulemaking said, "Test systems are sets of IVDs—for example, reagents, instruments, specimen collection devices, software, and other related materials—that function together to produce a test result." Medical Devices; Laboratory Developed Tests, 88 Fed. Reg. 68,006, 68,017 (proposed Oct. 3, 2023) (to be codified at 21 C.F.R. § 809.3(a)) ("NPRM"). An earlier draft guidance from FDA gave as an example of an LDT a situation in which "[t]he laboratory uses general purpose reagents and analyte specific reagents combined with general

[4] Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition. (2003), https://medical-dictionary.thefreedictionary.com/in+vitro.
[5] *Id.*, https://medical-dictionary.thefreedictionary.com/reagent.

laboratory instruments and develops a testing protocol, that together constitute a test system."[6] The entire system of reagents, instruments, specimen collection devices, software, and testing protocols functioning together within a laboratory is not a reagent (*in vitro* or otherwise), nor an instrument, nor a "similar or related article." The system functioning together is not an article of any kind because it is an intangible concept. It encompasses the services clinical laboratories provide. The word *article* refers to a tangible thing and does not include services. *Fortin v. Marshall*, 608 F.2d 525, 527-28 (1st Cir. 1979); *Wilton Meadow Ltd. Partnership v. Coratolo*, 14 A.3d 982, 987 (Conn. 2011).

The context of the word *article*—the rest of the Act—shows that a system is not the type of article that can be a device. Far too many provisions of the Act are simply incompatible with the notion that an article or a device can be the sort of system that encompasses LDTs.

The Act refers to characteristics of devices that LDTs cannot possess. Devices move: they have "movement in interstate commerce." 21 U.S.C. § 373(a). They can be imported or exported. *Id.* § 381. Devices can be packed, stored, and installed. *Id.* §§ 351(h), 360b, 360h(b)(1)(A)(iii), 360j(f)(1). A device can be replaced with an equivalent device that is in conformity with the Act. *Id. §* 360h(b)(2)(B). Another remedy available under the Act is an order "[t]o refund the purchase price of the device (less a reasonable allowance for use if such device has been in the possession of the device user for one year or more . . .)." *Id.* § 360h(b)(2)(C). An LDT does not have a purchase price and it is not in the possession of the device user.

Furthermore, devices are supposed to be labeled. If the label is false or misleading or does not bear adequate instructions, the device is misbranded. *Id.* § 352(a), (f). It is unclear how the

[6] Food and Drug Administration, Framework for Regulatory Oversight of Laboratory Developed Tests: Draft Guidance at 5 (Oct. 3, 2014), https://web.archive.org/web/20240501170534/https://www.fda.gov/media/89841/download.

system that constitutes an LDT could be labeled with adequate instructions. Without a label, it would be misbranded unless the secretary of health and human services promulgates regulations exempting it under § 352(f). The Final Rule does not contain such an exemption.

An important characteristic of devices is that they are for commercial distribution. Commercial distribution is an element of requirements, prohibitions, remedies, exemptions, and classifications with respect to devices. *Id.* §§ 360(j); 360(k); 360c(c), (f); 360e(b)(1), (i)(1); 360h(a)(1), (b)(1)(A)(i); 360j(b)(1)(C), (g)(2)(C). FDA defines *commercial distribution* as "any distribution of a device intended for human use which is held or offered for sale but does not include the following: (1) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company. . . ." 21 C.F.R. § 807.3(b). The exception for internal or interplant transfer excludes LDTs. Any movement of LDTs is internal or interplant transfer, not distribution. LDTs are not transferred or distributed outside of laboratories "because they are the entities that generally perform the tests." NPRM, 88 Fed. Reg. at 68,018. LDTs, the preamble to the Final Rule states, "are often used in laboratories outside of the patient's healthcare setting." 89 Fed. Reg. at 37,289.

The preamble to the Final Rule struggles in vain to explain away some of these inconsistencies between the Act and its interpretation of *device*. But to argue that it is sufficient that some, although not all, provisions of the Act can be applied to LDTs is no answer to the disjunction between the Act and the Final Rule.

B. The Protracted Conflict

This disjunction is not new. Until this year FDA and the rule did not claim jurisdiction over LDTs, but since its adoption in 1973, the rule has provided that in vitro diagnostic products

including systems for use in diagnosis are devices.[7] The rule predates the MDA and its amended definition of device by three years. From its very beginning, this rule has conflicted with the statute. Before the MDA, the Act defined *device* as follows.

> The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

Federal Food, Drug, and Cosmetic Act, Pub. L. 75-717, § 201(h), 52 Stat. 1040, 1041 (1938).

This definition does not include in vitro diagnostic products including systems for use in diagnosis. The MDA did not change that. FDA argues that the MDA at least did not exclude them: it "retained the same terms from the device definition in the 1938 Act, without any exemption for 'systems,' 'assays,' 'tests,' or 'laboratory developed tests.'" 89 Fed. Reg. at 37,330. This assertion is, as the D.C. Circuit once wrote, "True, but so what? The already capacious U.S. Code would require even more volumes if Congress could be clear only by ruling out every possible limitation on statutory language." *Shays v. Fed. Election Comm'n*, 414 F.3d 76, 108 (D.C. Cir. 2005).

FDA further asserts that "[i]f Congress had disagreed with FDA's interpretation, it had the opportunity to clarify that in the MDA, but it did not do so." 89 Fed. Reg. at 37,330. However, Congress *did* clarify the definition in the MDA. It adopted a definition that was broader than the existing definition in the Act but narrower than the definition in the 1973 regulation. It is narrower than the 1973 regulation because, as noted, it does not include in vitro diagnostic products including systems. Rather, the relevant language is "in vitro reagent, or other similar or related article." FDA argues that this language clarified "that IVD systems are devices and not drugs" and

[7] Labeling Requirements and Procedures for Development of Standards for In Vitro Diagnostic Products for Human Use, 38 Fed. Reg. 7,096, 7,098 (Mar. 15, 1973) (to be codified at 21 C.F.R. § 167.1(a)).

that "the goal was to clarify that all in vitro diagnostic products were devices rather than drugs." 89 Fed. Reg. at 37,330. In support of those assertions, FDA cites Senate Report Number 93–670, stating that it "explain[s], with respect to nearly identical language, that '[t]he Committee recognizes that there is confusion at the present time about whether certain articles are to be treated as devices or drugs under the Food, Drug and Cosmetic Act. Therefore, the Committee reported bill has carefully defined 'device' so as to specifically include implants, in vitro diagnostic products, and other similar or related articles.'" 89 Fed. Reg. at 37,330 (quoting S. Rpt. No. 93–670 at 16 (Jan. 29, 1974)).

The use of this report to support FDA's position is wrong both technically and substantively. It is wrong technically because Senate Report Number 93-670 reported out favorably S. 2368, which died at the end of the 93rd Congress. In the 94th Congress, however, Senate Report Number 94-33 reported out favorably S. 510, which was enacted. Senate Report Number 94-33 contains the same assertion that "the Committee reported bill has carefully defined 'device' so as to specifically include implants, in vitro diagnostic products, and other similar or related articles." S. Rep. No. 94-33 at 17 (Mar. 11, 1975). Reliance upon that statement is wrong substantively because the reported bill did not "specifically include . . . in vitro diagnostic products." It specifically included, as does the enacted law, in vitro reagents, *id.* at 33, 34, which is a narrower term and not "nearly identical language." One sentence in a committee report cannot override a statute's clear and unambiguous language. *St. Tammany Parish, ex rel. Davis v. Fed. Emergency Mgmt. Agency*, 556 F.3d 307, 323 (5th Cir. 2009).

Thus, the MDA did not ratify the terms of the rule. The rule remained incompatible with the statutory text. Indeed with respect to in vitro diagnostic products including systems, FDA has not exercised enforcement discretion so much as wishful thinking. Section 809.3(a) as revised in

the Final Rule is even more incompatible with the statutory text because it provides that the intangible system of elements and processes that function together to produce diagnostic test results in a laboratory are products that "are devices as defined in section 201(h)(1)" of the Act. FDA's aggrandizement expands the definition of device in section 201(h)(1) of the Act beyond recognition. As Plaintiffs American Clinical Laboratory Association, HealthTrackRX Indiana, Inc. and HealthTrackRX, Inc. correctly allege in their complaint, the text and context of section 201(h)(1) do not allow such a distortion of its plain meaning. *See* Dkt. #1 at ¶ 134. FDA's Final Rule conflicts with the law not only in what it adds but also in what it retains.

II. FDA Has Not Exercised Its Authority Consistently with the Requirements of the Administrative Procedure Act.

In its comment on the proposed rule, Amicus commented that FDA had failed to conduct the federalism analysis required of it by Executive Order No. 13,132, 3 C.F.R. § 206 (2000). Adhering the fiction that it is adopting a change only in enforcement policy, FDA responded:

> [T]he requirement for a federalism summary impact statement applies to the proposed amendment to § 809.3 (and not the phaseout policy), and because the proposed regulation would not establish any new requirements, it would not have any federalism implications under E.O. 13132. Moreover, even if the requirement for a federalism summary impact statement were to apply to the phaseout policy, the policy does not have federalism implications because it is not establishing any new requirements.

89 Fed. Reg. at 37,436; *see also id.* at 37,362. If neither the regulation nor the phaseout policy established any new requirements, then they most unnecessarily excited the agency, commentators, and the litigants. But from the point of view of a regulated entity seeking to avoid trouble with FDA, the complexities of the phaseout policy and its five stages and their exceptions, 89 Fed. Reg.

at 37,295-37,311, have to be read as requirements. Each of the five stages expressly sets forth what compliance FDA will expect.[8]

While FDA might try to dispute that statement, it would have a hard time denying that the phaseout policy is a policy. To be more precise, it is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." That is the pertinent part of the Administrative Procedure Act's definition of a rule. 5 U.S.C. § 551(4).

This definition has three distinct elements,[9] each of which is present. The first element that the phaseout policy meets is that a rule is the whole or a part of any agency statement. The phaseout policy is part of FDA's statement published in the Federal Register. The second element is that the statement has general or particular applicability and future effect. The statement applies generally to manufacturers of LDTs and goes into effect in stages in the future. Finally, the statement setting forth the phaseout policy unquestionably prescribes a policy. It also prescribes procedures of the agency. The only difference between those procedures and most others is that FDA reserves the

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[8] • *Stage 1:* beginning 1 year after the publication date of this final rule, FDA will expect compliance with MDR requirements, correction and removal reporting requirements, and QS requirements under § 820.198 (complaint files).
• *Stage 2:* beginning 2 years after the publication date of this final rule, FDA will expect compliance with requirements not covered during other stages of the phaseout policy, including registration and listing requirements, labeling requirements, and investigational use requirements.
• *Stage 3:* beginning 3 years after the publication date of this final rule, FDA will expect compliance with QS requirements under part 820 (other than requirements under § 820.198 (complaint files), which are already addressed in stage 1).
• *Stage 4:* beginning 3½ years after the publication date of this final rule, FDA will expect compliance with premarket review requirements for high-risk IVDs offered as LDTs, unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion for the pendency of its review.
• *Stage 5:* beginning 4 years after the publication date of this final rule, FDA will expect compliance with premarket review requirements for moderate-risk and low-risk IVDs offered as LDTs (that require premarket submissions), unless a premarket submission has been received by the beginning of this stage in which case FDA intends to continue to exercise enforcement discretion for the pendency of its review. 89 Fed. Reg. at 37,307.

[9] *Abbs v. Sullivan*, 756 F. Supp. 1177, 1187 (W.D. Wis. 1990), *vacated on jurisdictional grounds*, 963 F.2d 918 (7th Cir.1992).

prerogative to ignore compliance with its procedures. For example, "FDA generally does not intend to enforce against IVDs offered as LDTs for lacking premarket authorization after a complete 510(k) or De Novo request has been submitted until FDA completes its review of the submission, provided that the 510(k) or De Novo request has been submitted within the 4-year timeframe." *Id.* at 37,310-11.

Since the policy is a rule, the Administrative Procedure Act requires it to be published as a rule in the Federal Register, 5 U.S.C. § 552(a)(1), even if it is exempt from the notice and comment requirements of section 553. *Preminger v. Sec'y of Veterans Affairs*, 632 F.3d 1345, 1380 (Fed. Cir. 2011). Publication in the preamble of a final rule does not satisfy that requirement: it is a legal nullity. *Natural Resources Def. Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009).

The ill-conceived phaseout policy was not a proper response to comments calling FDA's attention to the enormous costs of its proposal, including the economic cost of laboratories going out of business because they cannot bear all the costs of compliance and the opportunity costs to patients resulting from unavailable tests, both of which the proposal failed to consider. As Plaintiff American Clinical Laboratories Association, HealthTrackRX Indiana, Inc., and HealthTrackRX, Inc. correctly allege in their complaint, FDA has not exercised its authority consistent with the requirements of reasoned decision-making under the Administrative Procedure Act; its attempt to announce a complex phaseout policy in a preamble underscores how unreasonable it is for FDA to outlaw an entire sector of professional services, thereby imperiling reliance interests. *See* Dkt. #1 at ¶¶ 140-141.

CONCLUSION

For the foregoing reasons, Plaintiffs' motions for summary judgment should be granted. As Plaintiffs requested in their prayers for relief, the Court should vacate FDA's Final Rule and enjoin its implementation. The rule should be vacated in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies this document was filed electronically in compliance with Local Rule CV-5(a). As such, it was served on all counsel of record on October 7, 2024.

/s/ Casey Griffith

Casey Griffith